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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/719,017	03/05/2001	Jerome Pierrard	PH-98/032	3131

7590

09/30/2002

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EXAMINER

SLOBODYANSKY, ELIZABETH

ART UNIT	PAPER NUMBER
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1652

DATE MAILED: 09/30/2002

62

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/719,017

Applicant(s)

PIERRARD ET AL.

Examiner

Elizabeth Slobodyansky

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 5 March 2001; 9 October 2001.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 21-44 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 21-38 and 40-43 is/are rejected.
- 7) ☒ Claim(s) 39 and 44 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>11</u> . | 6) <input type="checkbox"/> Other: _____ |

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DETAILED ACTION

The instant application is a 371 of PCT/FR99/01343.

The preliminary amendment filed March 5, 2001 amending the specification to correct typographical errors, canceling claims 1-20 and adding claims 21-44 has been entered.

The preliminary amendment filed October 9, 2001 amending the specification to insert references to sequence identifiers has been entered.

Claims 21-44 are pending.

Priority

Receipt is acknowledged of papers submitted under 35 U.S.C. 119(a)-(d), which papers have been placed of record in the file.

Information Disclosure Statement

The information disclosure statement filed March 5, 2001 fails to comply with 37 CFR 1.98(a)(3) because it does not include a concise explanation of the relevance, as it is presently understood by the individual designated in 37 CFR 1.56(c) most knowledgeable about the content of the information, of each patent listed that is not in the English language. It has been placed in the application file, but the information referred to therein has not been considered.

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The relevant references are lined through in pencil on form PTO-1449.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 21-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

Claim 21 is drawn to an industrial process for expressing heterologous proteins in *E. coli* W host cell. Therefore, the claims are drawn to a method of use of a genus of expression systems and specific fermentation conditions. The specification does not describe what renders the system "suitable" to be used in "industrial" process vs a laboratory process, for example. The specification does not describe what renders the conditions "suitable" to provide the requisite results. With respect to specific fermentation conditions, the specification does not describe the systems that require said specific conditions.

The specification discloses only systems based on pRPA-BCAT4 (Examples) that under the specific conditions produce high level of nitrilase which is insufficient to

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put one of skill in the art in possession of the attributes and features of all species within the claimed genus. Therefore, one skilled in the art cannot reasonably conclude that the applicant had possession of the claimed invention at the time the instant application was filed.

The following is a provisional rejection that would apply over specific embodiments ('suitable system') of the invention if they were claimed. Such embodiments are non-obvious.

Claims 21-38 and 40-43 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

It is apparent that pRPA-BCAT4 and derivative plasmids are required to practice the claimed invention. As a required element it/they must be known and readily available to the public or obtainable by a repeatable method set forth in the specification. If it/they is/are not so obtainable or available, the enablement requirements of 35 U.S.C. § 112, first paragraph, may be satisfied by a deposit of the microorganism(s). See 37 C.F.R. § 1.802.

It is not apparent if the microorganism(s) are readily available to the public. The specification must contain the date that the microorganism(s) was/were

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deposited, the name of the microorganism(s) and the address of where the microorganism(s) was/were deposited.

If the deposit(s) has/have been made under the terms of the Budapest Treaty, then an affidavit or declaration by Applicants or someone associated with the patent owner who is in a position to make such assurances, or a statement by an attorney of record over his/her signature, and registration number, stating that the specific strain(s) has/have been deposited under the Budapest Treaty and that all restrictions imposed by the depositor on the availability to the public of the deposited material will be irrevocably removed upon the granting of a patent, would satisfy the deposit requirements. See 37 C.F.R. § 1.808.

If the deposit(s) has/have not been made under the Budapest Treaty, then in order to certify that the deposit(s) meets the criteria set forth in 37 C.F.R. § 1.801-1.809, Applicant(s) may provide assurance of compliance by an affidavit or declaration, or by a statement by an Attorney of record over his/her signature and registration number, showing that:

(a) during the pendency of this application, access to the invention will be afforded to the Commissioner upon request;

(b) all restrictions upon availability to the public will be irrevocably removed upon granting of the patent;

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(c) the deposit(s) will be maintained in a public depository for a period of 30 years or 5 years after the last request or for the effective life of the patent, whichever is longer;

(d) a viability statement in accordance with the provisions of 37 C.F.R. § 1.807; and

(e) the deposit will be replaced should it become necessary due to inviability, contamination or loss of capability to function in the manner described in the specification.

In addition, the identifying information set forth in 37 C.F.R. § 1.809 (d) should be added to the specification. See 37 C.F.R. § 1.803-1.809 for additional explanation of these requirements.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 21, with dependent claims 22-44, is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 21 recites the limitation "the industrial process". It is unclear what is the essential property that makes the process "industrial". The specification defines the term by non-limiting examples (page 10, lines 4-14).

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Usually the words expressing "in" not "into" *E. coli* are used.

The term "high" in claim 24 is a relative term which renders the claim indefinite. The term "high" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention.

The claims recite "*E. coli*" bacteria strain W host cell. It appears that "bacterial" or "bacterium" is intended. However, either term is redundant.

With regard to claim 38 it is unclear which molecules in addition to the sequence of SEQ ID NO:1 are encompassed by the term " P_{trp} ".

Claim 41 is redundant as dependent from claim 40. Enzymes by definition are useful for the biocatalysis of chemical reactions.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 21-24, 34, 35, 40 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by Cambiaghi et al.

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Cambiaghi et al. (US Patent 5,424,196, form PTO-1449, reference AD) teach expression of a heterologous enzyme, GI-7-ACA acylase in *E. coli* ATCC 9637 (columns 15-17, Example 9). They teach that *E. coli* ATCC 9637 has high GI-7-ACA acylase productive capacity (column 17, lines 46-48). They teach a derivative of *E. coli* ATCC 9637 selected by clonal selection and genetic manipulation. They teach sources of nitrogen such as yeast extract (column 17, lines 55-60).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 25-28, 33-38 and 43 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cambiaghi et al. in view of Makrides et al.

The teachings of Cambiaghi et al. are outlined above.

Makrides et al. review strategies for high-level expression of genes in *E. coli*. They teach advantages of P_{trp} promoter (pages 513-514). They teach fermentation strategies (page 525).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use optimal conditions for fermenting *E. coli* transformed with a

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DNA encoding a heterologous protein under control of P_{trp} . *E. coli* is the most studied and widely used host system for these purposes and the various conditions for its fermentation are known in the art. Absent unexpected results, various conditions are matter of choice.

Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Cambiaghi et al. in view of Lee et al.

The teachings of Cambiaghi et al. are outlined above.

Lee et al. (form PTO-1449) teach high density cultivation of *E. coli* W using sucrose as a carbon source (page 971, introduction).

It would have been obvious to one of ordinary skill in the art at the time the invention was made to use sucrose as a carbon source for optimal fermentation conditions of *E. coli* W.

Claim 42 is rejected under 35 U.S.C. 103(a) as being unpatentable over Cambiaghi et al. in view of Petre et al.

The teachings of Cambiaghi et al. are outlined above.

Petre et al. (US Patent 5,635,391) teach expression of a heterologous nitrilase in *E. coli* under control of P_{trp} (claims 6-8). They teach the importance of nitrilase for conversion nitriles to carboxylates (column 1, lines 19-37).

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It would have been obvious to one of ordinary skill in the art at the time the invention was made to express nitrilase instead of GI-7-ACA acylase in *E. coli* W.

Allowable Subject Matter

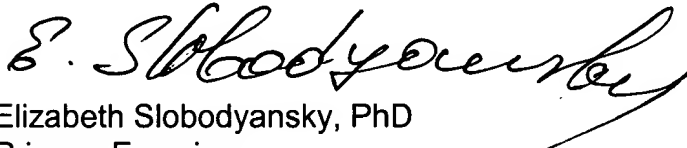
Claim 44 would be allowable if rewritten to overcome the rejection(s) under 35 U.S.C. 112, second paragraph, set forth in this Office action and to include all of the limitations of the base claim and any intervening claims.

Claim 39 amended to be drawn to a method of use of a host cell of claim 44 for the production of heterologous proteins would be allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth Slobodyansky whose telephone number is (703) 306-3222. The examiner can normally be reached Monday through Friday from 9:30 AM to 6:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX phone number for Technology Center 1600 is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Center receptionist whose telephone number is (703) 308-0196.


Elizabeth Slobodyansky, PhD
Primary Examiner

September 27, 2002